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UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF NEVADA

UNITED STATES OF AMERICA Plaintiff, v. AFFINITYLIFESTYLES.COM, INC., and REAL WATER, INC., corporations, and BRENT A. JONES and BLAIN K. JONES, individuals. Defendants.	Case No. 21-cv-959 COMPLAINT FOR A PERMANENT INJUNCTION

Plaintiff, the United States of America, on behalf of the United States Food and Drug Administration ("FDA") alleges:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 332(a), to halt the manufacture and distribution of adulterated and/or misbranded bottled drinking water and chemical concentrate. Defendants' bottled drinking water has been associated with five cases of acute liver failure in children. Plaintiff seeks an injunction to restrain and enjoin Defendants from directly or indirectly doing or causing the following acts:

A. Violating 21 U.S.C. § 331(uu), by operating a facility that manufactures, processes, packs, or holds food for sale in the United States, and not doing so in compliance with the hazard analysis and risk-based preventive controls requirements in 21 U.S.C. § 350g;

B. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4) and/or misbranded within the meaning of 21 U.S.C. § 343(i)(2); and

C. Violating 21 U.S.C. § 331(k), by causing articles of food that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) and/or misbranded within the meaning of 21 U.S.C. § 343(i)(2).

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a).

3. Venue in this district is proper under 28 U.S.C. § 1391.

THE PARTIES

4. Plaintiff, the United States of America, brings this action on behalf of FDA, the agency mandated to protect the public health by, among other things. ensuring the safety of the U.S. food supply, including, but not limited to, bottled drinking water.

5. Defendant AffinityLifestyles.com, Inc. ("Affinity") is a Nevada corporation operating under Nevada Business ID, NV19981130088, and located at 3773 Howard Hughes Parkway, Suite 500S, Las Vegas, Nevada 89169. Affinity is the majority shareholder of Defendant Real Water, Inc.

6. Defendant Real Water, Inc. ("Real Water") is a Delaware corporation, doing business in Nevada, under Nevada Business ID, NV20181191189, with addresses at 3208 W. Desert Inn Rd, Las Vegas, NV 89102 and 6018 E. Main Street, Mesa, Arizona 85205.

7. Real Water manufactures bottled drinking water and a proprietary chemical concentrate ("E^2 Concentrate") at 1180 Center Point Drive, Suite 200, Henderson, Nevada 89102 (the "Henderson Facility"), within the jurisdiction of this Court.

8. Real Water also manufactures bottled drinking water at 6018 E. Main Street, Mesa, Arizona 85205 (the "Mesa Facility").

9. Defendants distribute bottled drinking water from the Henderson Facility and the Mesa Facility under the brands "Re^{2}al Water Drinking Water" and "Re^{2}al Alkalized Water," respectively. "Re^{2}al Water" is used herein to refer to either brand of Defendants' bottled drinking water.

10. Defendants repackage E^2 Concentrate at the Mesa Facility and distribute it under the brand "Re^{2}al Alkalized Water Concentrate."

11. Defendant Brent A. Jones is the President and Director of Affinity and Real Water. He is responsible for purchasing, marketing, and sales at Real Water. Brent A. Jones is a resident of Nevada, who performs his duties at the Henderson Facility, within the jurisdiction of this Court.

12. Defendant Blain K. Jones is the Vice President, Secretary, and Treasurer of Real Water, and the Secretary and Treasurer of Affinity. He is responsible for manufacturing, distribution, and employee training at Real Water. Blain K. Jones is a resident of Nevada, who performs his duties at the Henderson Facility, within the jurisdiction of this Court.

13. Upon information and belief, Defendants Brent A. Jones and Blain K. Jones are the only individuals who know the formula for E^2 Concentrate.

14. Upon information and belief, Defendant Blain K. Jones is the sole individual responsible for manufacturing E^2 Concentrate.

DEFENDANTS' PRODUCTS

15. Defendants manufacture, process, prepare, bottle, pack, label, hold, and distribute articles of food within the meaning of 21 U.S.C. § 321(f), namely Re^{2}al Water and E^2 Concentrate.

16. Defendants manufacture E^2 Concentrate at the Henderson Facility using materials shipped from outside Nevada, including potassium hydroxide provided by a chemical company located in Arizona.

17. To manufacture E^2 Concentrate, Defendants first process municipal tap water by carbon filtration, reverse osmosis filtration, ultraviolet light filtration, and ozone filtration, and then Defendants mix this processed water with potassium hydroxide, potassium bicarbonate, and magnesium chloride.

Next, Defendants claim to use a proprietary "ionizer" apparatus to apply an electrical current to this mixture, which allegedly creates positively-charged and negatively-charged solutions. Defendants then discard the positively-charged solution and store the negatively-charged solution as E^2 Concentrate.

18. Defendants use E^2 Concentrate for manufacturing Re^2al Water at the Henderson Facility. Defendants also send E^2 Concentrate to the Mesa Facility for manufacturing Re^2al Water there, and for repackaging the E^2 Concentrate into retail bottles.

19. Defendants manufacture Re^2al Water by adding E^2 Concentrate and potassium hydroxide to municipal tap water that has been processed as described in paragraph 17. Defendants mix these ingredients in a large tank, and then fill containers with this mixture for distribution as Re^2al Water.

20. Defendants distribute 5-gallon containers of Re^2al Water from the Henderson Facility both to customers within Nevada and to customers located outside of Nevada, including Arizona and California. Defendants distribute 500-milliliter (mL), 1-liter (L), 1.5-L, and 1-gallon containers of Re^2al Water from the Mesa Facility to distributors in Arizona, California, and Nevada. Defendants distribute 4-ounce (oz) bottles of E^2 Concentrate from the Mesa Facility to online consumers throughout the United States.

21. Defendants market Re^2al Water as "premium" drinking water that is a "clean," "healthy" alternative to tap water.

22. Defendants market E^2 Concentrate as a taste enhancer that consumers can add to liquids, including, but not limited to, tea, coffee, and wine.

23. Defendants intend for Re^2al Water and E^2 Concentrate to be consumed with no further processing. It is therefore crucial for Defendants to properly manufacture, process, prepare, bottle, pack, hold, and distribute Re^2al Water and E^2 Concentrate to minimize the potential for chemical and microbial contamination and reduce the risk of illness to consumers.

PREVENTIVE CONTROLS REQUIREMENTS

24. The Federal Food, Drug, and Cosmetic Act requires that the owner, operator, or agent in charge of a facility evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, and identify and implement preventive controls to significantly minimize or prevent the

occurrence of those hazards and provide assurances that such food is not adulterated. See 21 U.S.C. § 350g (Hazard analysis and risk-based preventive controls).

25. The hazard analysis and risk-based preventive controls requirements set forth at 21 C.F.R. Part 117, Subpart C ("Human Food Preventive Control Regulations"), implement 21 U.S.C. § 350g, and were promulgated to better protect the public health by, among other things, ensuring the production of safe and sanitary food through hazard analysis and risk-based preventive controls. See 21 U.S.C. § 350g(n)(1)(A). Failure to comply with the Human Food Preventive Control Regulations violates the Federal Food, Drug, and Cosmetic Act. See 21 U.S.C. § 331(uu) and 21 C.F.R. § 117.1(b); see also Final Rule, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls in Human Food, 80 Fed. Reg. 55,908 (Sept. 17, 2015).

26. The hazard analysis requirements require the owner, operator, or agent in charge of a food facility to "conduct a hazard analysis to identify . . . known or reasonably foreseeable hazards . . . to determine whether there are any hazards requiring a preventive control" for each type of food manufactured, processed, packed, or held at the facility. 21 C.F.R. § 117.130(a) (Requirement for a hazard analysis); 21 U.S.C. § 350g(b). Hazards can be biological, chemical, or physical, and they can be naturally occurring, unintentionally introduced, or intentionally introduced for purposes of economic gain. See 21 U.S.C. § 350g(b); 21 C.F.R. § 117.130(b) (Hazard identification).

27. The owner, operator, or agent in charge of a food facility must, among other things, identify and implement preventive controls to provide assurances that any hazards requiring a preventive control are significantly minimized or prevented, and the food manufactured, processed, packed, or held by a facility is not adulterated under 21 U.S.C. § 342. See 21 U.S.C. § 350g(c); 21 C.F.R. § 117.135 (Preventive controls).

28. Preventive controls include, as appropriate to the food and facility, process controls, sanitation controls, supply-chain controls, a recall plan, as well as any other controls necessary to provide assurances that the food is not adulterated under 21 U.S.C. § 342. 21 U.S.C. § 350g(c); 21 C.F.R. § 117.135(c).

29. The preventive controls requirements require monitoring procedures to provide assurance that the preventive controls are being consistently performed, see 21 U.S.C. § 350g(d) and 21 C.F.R. § 117.145 (Monitoring); corrective action procedures to be taken if preventive controls are not properly implemented or found to be ineffective, see 21 U.S.C. § 350g(e) and 21 C.F.R. § 117.150 (Corrective actions and corrections); and procedures to verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing hazards, see 21 U.S.C. § 350g(f) and 21 C.F.R. § 117.165 (Verification of implementation and effectiveness).

30. The preventive controls requirements additionally require documentation of monitoring and corrective actions in accordance with 21 C.F.R. §§ 117.145 and 117.150 in records that are subject to review in accordance with 21 C.F.R. § 117.165. See 21 U.S.C. § 350g(g) (Recordkeeping).

31. The preventive controls requirements further require that the owner, operator, or agent in charge of a food facility prepare a written food safety plan that includes the hazard analysis, preventive controls, supply-chain program, recall plan, and monitoring, corrective action, and verification procedures described above. See 21 U.S.C. § 350g(h) (Written Plan and Documentation); 21 C.F.R. § 117.126 (Food safety plan).

Defendants' Violations

32. Defendants violate the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(uu), by operating a facility that manufactures, processes, packs, or holds food for sale in the United States, in a manner that does not comply with the hazard analysis and risk-based preventive controls requirements of 21 U.S.C. § 350g.

33. Defendants fail to comply with the hazard analysis and preventive controls requirements by, among other things, their:

A. Failure to identify and evaluate any known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at Defendants' facilities to determine whether there are hazards requiring a preventive control, in violation of 21 U.S.C. § 350g(b) and 21 C.F.R. § 117.130;

B. Failure to identify and implement preventive controls to provide assurances that the food manufactured, processed, packed, or held at Defendants' facilities is not adulterated under 21 U.S.C. § 342, in violation of 21 U.S.C. § 350g(c) and 21 C.F.R. § 117.135;

C. Failure to monitor the effectiveness of preventive controls to provide assurances that the food manufactured, processed, packed, or held by Defendants' facilities is not adulterated under 21 U.S.C. § 342, in violation of 21 U.S.C. § 350g(d) and 21 C.F.R. § 117.145;

D. Failure to establish appropriate corrective action procedures to ensure that the food manufactured, processed, packed, or held by Defendants' facilities and introduced into interstate commerce is not adulterated, in violation of 21 U.S.C. § 350g(e) and 21 C.F.R. § 117.150(b);

E. Failure to verify that preventive controls identified and implemented to provide assurances that the food manufactured, processed, packed, or held by Defendants' facilities is not adulterated under 21 U.S.C. § 342 are adequate to control the hazards so identified, in violation of 21 U.S.C. § 350g(f) and 21 C.F.R. § 117.165(a);

F. Failure to establish and implement a risk-based supply-chain program for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control, in violation of 21 U.S.C. § 350g(c) and 21 C.F.R. §§ 117.135(c)(4) and 117.405; and

G. Failure to develop a written food safety plan, in violation of 21 U.S.C. § 350g(h) and 21 C.F.R. § 117.126.

FOOD ADULTERATION

34. Food is adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act "if it has been prepared, packed, or held under insanitary conditions whereby it may be have become contaminated with filth, or whereby it may have been rendered injurious to health." 21 U.S.C. § 342(a)(4).

35. Manufacturers that process, bottle, hold, or ship bottled drinking water must comply with FDA's current good manufacturing practice ("CGMP") requirements for bottled drinking water at 21 C.F.R. Part 129 ("Bottled Water CGMP Regulations"). See 21 C.F.R. § 129.1. The Bottled Water

CGMP Regulations were promulgated to ensure that bottled drinking water is safe for human consumption and that it has been processed, bottled, held, and transported under sanitary conditions. 21 C.F.R. § 129.1. Manufacturing according to Bottled Water CGMP Regulations means that the facilities, methods, practices, and controls used in the processing, bottling, holding, and transporting of bottled drinking water are administered in conformity with CGMP. 21 C.F.R. § 129.1.

36. Among other things, failure to follow Bottled Water CGMP Regulations can render bottled drinking water adulterated within the meaning of 21 U.S.C. § 342(a)(4). See 21 C.F.R. § 129.1.

Defendants' Violations

37. Defendants violate the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4).

38. Defendants violate the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(k), by causing articles of food that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4).

39. Defendants fail to comply with Bottled Water CGMP Regulations by, among other things, their:

A. Failure to adequately clean and sanitize product water-contact surfaces of all multiservice containers, utensils, pipes, and equipment used in the transportation, processing, handling, and storage of product water, in violation of 21 C.F.R. § 129.37 (Sanitary operations), as those terms are defined by 21 C.F.R. § 129.3 (e.g., "product water" is processed water that a plant uses for bottled drinking water, and "multiservice containers" are containers intended to be used more than once);

B. Failure to process product water under processes and controls necessary to ensure that Defendants' treatment of their product water is effective and will not adulterate the bottled product, in violation of 21 C.F.R. § 129.80(a);

C. Failure to adequately sample and test cleaning and sanitizing solutions to assure adequate performance in the cleaning and sanitizing operations, in violation of 21 C.F.R. § 129.80(c);

D. Failure to identify each unit package with a production code that identifies the batch and date produced, and record and maintain information as to the kind of product, volume produced, date produced, lot code used, and the distribution of product to wholesale and retail outlets, in violation of 21 C.F.R. § 129.80(e);

E. Failure to adequately monitor and record the performance of their filling, capping, and sealing process to assure that containers and closures are free from contamination, in violation of 21 C.F.R. § 129.80(f); and

F. Failure to adequately analyze product samples to assure that production of bottled drinking water complies with applicable standards, laws, and regulations, in violation of 21 C.F.R. § 129.80(g).

MISBRANDED FOOD

40. A food is misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act if, among other things, it is fabricated from two or more ingredients and its label fails to bear the common or usual name of each ingredient. 21 U.S.C. § 343(i)(2).

41. Food must comply with labeling requirements that declare the ingredients by listing them by common or usual name in descending order of predominance by weight on either the principle display panel or the information panel. *See* 21 C.F.R. § 101.4 (Food; designation of ingredients).

Defendants' Violations

42. Defendants violate the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing to be introduced or delivered for introduction into interstate commerce, articles of food that are misbranded under 21 U.S.C. § 343(i)(2).

43. Defendants violate the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(k), by causing articles of food that are held for sale after shipment of one or more components in interstate commerce to become misbranded under 21 U.S.C. § 343(i)(2).

44. Defendants cause their Re^{2}al Water and E^2 Concentrate to be misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act as follows:

A. Defendants' Re^{2}al Water product labels do not list by common or usual name all ingredients, and ingredients of multi-component ingredients, including potassium hydroxide and magnesium chloride, in violation of 21 U.S.C. § 343(i)(2) and 21 C.F.R. § 101.4; and

B. Defendants' E^2 Concentrate product labels do not list by common or usual name all ingredients, including potassium bicarbonate, in violation of 21 U.S.C. § 343(i)(2) and 21 C.F.R. § 101.4.

EVIDENCE OF VIOLATIONS

45. In March/April 2021, FDA inspected Defendants' Henderson and Mesa Facilities, in response to reports of five cases of acute liver failure in children and infants potentially linked to consumption of Defendants' Re^{2}al Water. During these inspections, FDA investigators documented significant deviations from preventive controls requirements and Bottled Water CGMP Regulations.

Preventive Controls

46. Defendants' significant deviations from preventive controls requirements included, but were not limited to, the following:

A. Failure to identify and evaluate any known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at Defendants' facilities to determine whether there are hazards requiring a preventive control, in violation of 21 U.S.C. § 350g(b) and 21 C.F.R. § 117.130. Specifically, Defendants have not performed a hazard analysis of E^2 Concentrate to identify chemical hazards requiring a preventive control due to misformulation of E^2 Concentrate. Defendants have no documentation of the ingredients or manufacturing process for E^2 Concentrate to ensure that excessive amounts of chemical ingredients are not added or improperly mixed, or that the E^2 Concentrate is not contaminated with environmental pathogens during processing. Defendants have also not performed a hazard analysis to identify biological hazards, including environmental pathogens, requiring a preventive control due to recontamination during the formulating or mixing of the E^2 Concentrate. The E^2 Concentrate sold directly to consumers does not undergo a lethal treatment, meaning a treatment that will significantly minimize any environmental pathogen prior to packaging, thus any biological contamination would be passed on to the consumer;

B. Failure to identify and implement preventive controls to provide assurances that the food manufactured, processed, packed, or held by Defendants' facilities is not adulterated under 21 U.S.C. § 342, in violation of 21 U.S.C. §350g(c) and 21 C.F.R. § 117.135. For example, FDA investigators observed at the Henderson and Mesa Facilities that Defendants have no written process control and/or supply-chain control procedures to ensure that the correct type and amount of chemicals are added to each batch of product water. Defendants also do not have written sanitation controls at the Henderson and Mesa Facilities to control the risk of recontamination with environmental pathogens during the mixing and bottling processes;

C. Failure to monitor the effectiveness of preventive controls to provide assurances that the food manufactured, processed, packed, or held at Defendants' facilities is not adulterated under 21 U.S.C. § 342, in violation of 21 U.S.C. § 350g(d) and 21 C.F.R. § 117.145. Specifically, Defendants do not have any monitoring records documenting Defendants' formulation and mixing steps of their E^2 Concentrate at the Henderson Facility, and do not have any monitoring records documenting Defendants' formulation and mixing steps of their Re^2al Water at the Henderson and the Mesa Facilities;

D. Failure to establish appropriate corrective action procedures to ensure that the food manufactured, processed, packed, or held by Defendants' facilities from and entering interstate commerce is not adulterated in violation of 21 U.S.C. § 350g(e) and 21 C.F.R. § 117.150(b). Specifically, Defendants did not implement or record appropriate corrective actions in response to illness complaints and equipment failure;

E. Failure to verify that preventive controls identified and implemented to provide assurances that the food manufactured, processed, packed, or held by Defendants' facilities is not adulterated under 21 U.S.C. § 342 are adequate to control the hazard so identified, in violation of 21 U.S.C. § 350g(f) and 21 C.F.R. § 117.165(a). Specifically, Defendants failed to collect and test environmental samples that verify the effectiveness of their sanitation controls to prevent contamination by environmental pathogens;

F. Failure to establish and implement a risk-based supply-chain program for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a

supply-chain-applied control, in violation of 21 U.S.C. § 350g(c) and 21 C.F.R. §§ 117.135(c)(4) and 117.405. Specifically, FDA investigators observed that Defendants do not have preventive controls at the Mesa Facility for the E^2 Concentrate received from the Henderson Facility to verify that the Henderson Facility is controlling the chemical hazard that could result due to misformulation of the E^2 Concentrate. Defendants also do not have records documenting the Mesa Facility's receipt of the E^2 Concentrate, which is needed for a valid supply-chain program; and

G. Failure to develop a written food safety plan, in violation of 21 U.S.C. § 350g(h) and 21 C.F.R. § 117.126. Defendants are required to have a written food safety plan that contains a hazard analysis, preventive controls, a supply-chain program, a recall plan, procedures for monitoring the preventive control implementation, corrective action procedures, and verification procedures, but they do not have such a plan for their E^2 Concentrate. Thus, Defendants have not taken adequate measures to protect against the hazards of chemical contamination in E^2 Concentrate or in Re^{2}al Water that contains E^2 Concentrate and is distributed directly to consumers.

Bottled Water CGMP

47. Defendants' significant deviations from CGMP regulations included, but were not limited to, the following:

A. Failure to adequately clean and sanitize product water-contact surfaces of all multiservice containers, utensils, pipes, and equipment used in the transportation, processing, handling, and storage of their product water, in violation of 21 C.F.R. § 129.37. For example, during the inspections at the Mesa and Henderson Facilities, FDA investigators observed that Defendants have not properly cleaned and sanitized the water tanks in which they mix processed municipal tap water with E^2 Concentrate, potentially leading to chemical and microbial contamination;

B. Failure to process product water under processes and controls necessary to ensure that Defendants' treatment of their processed product water is effective and will not adulterate the bottled product, in violation of 21 C.F.R. § 129.80(a). For example, during the inspection at the Henderson Facility, FDA investigators observed that Defendants use a combination of carbon, reverse osmosis, ultraviolet light, and ozone filtration to process municipal tap water prior to its use as an

ingredient in E^2 Concentrate and Re^2al Water. However, Defendants fail to record the results of any inspections of the equipment used for these processes, conditions found, and the performance or effectiveness of the equipment. In addition, at the Henderson and Mesa Facilities, the investigators observed that Defendants do not sample the processed municipal tap water to assure the effectiveness of these processes, potentially leading to impure and unsafe water;

C. Failure to adequately sample and test cleaning and sanitizing solutions to assure adequate performance in the cleaning and sanitizing operations, in violation of 21 C.F.R. § 129.80(c). For example, during the inspection at the Henderson Facility, FDA investigators observed that Defendants use recycled detergent and sanitizer water to clean and sanitize their reusable 5-gallon water containers that hold Re^2al Water, but fail to record the results of any sampling and testing of the recycled detergent and sanitizer water to assure adequate performance, potentially leading to chemical and microbial contamination;

D. Failure to identify each unit package with a production code that identifies the batch and date produced, and record and maintain information as to the kind of product, volume produced, date produced, lot code used, and the product distribution to wholesale and retail outlets, in violation of 21 C.F.R. § 129.80(e). For example, FDA investigators observed no production codes on unit packages of Re^2al Water held at the Henderson Facility. Defendants were unable to provide production records from the Mesa Facility. These failures further complicated recall and traceback activities;

E. Failure to adequately monitor and record the performance of their filling, capping, and sealing processes to assure that containers and closures are free from contamination, in violation of 21 C.F.R. § 129.80(f). Specifically, FDA investigators observed that Defendants do not monitor and record the performance of their filling, capping, and sealing operations, and they do not inspect and sample the containers and closures for bacteriological contamination; and

F. Failure to adequately analyze product samples to assure that production of bottled drinking water complies with applicable standards, laws, and regulations, in violation of 21 C.F.R. § 129.80(g). Specifically, Defendants fail to take and analyze representative product samples at least

once a week for total coliform organisms, fail to take and analyze representative product samples at least annually for chemical, radiological, physical, and radiological purposes, and fail to keep records of such analysis.

Illnesses

48. On March 13, 2021, FDA received information regarding five cases of acute non-viral hepatitis (resulting in acute liver failure) in infants and children that appeared to be associated with Re^{2}al Water. The patients are from four different households, and all consumed Re^{2}al Water prior to becoming ill.

49. FDA, the Centers for Disease Control and Prevention ("CDC"), and State health departments are investigating these illnesses and collecting additional data as part of an ongoing epidemiological investigation. To date, CDC has identified only one common exposure for the above five cases – Re^{2}al Water. No other common exposures, including medications, food, supplements, activities, travel history, or ill contacts have been reported or linked to the illnesses.

50. During the 2021 Inspections, FDA investigators documented that Defendants had received complaints of illness from consumers, including complaints of nausea and vomiting after consuming Re^{2}al Water.

51. After FDA warned consumers, restaurants, distributors, and retailers not to drink, cook with, sell, or serve Re^{2}al Water because of its association with the illnesses, FDA received additional consumer complaints of illnesses alleged to be caused by Re^{2}al Water.

WARNINGS

52. On March 16, 2021, FDA notified Defendants that Re^{2}al Water appeared to be associated with five cases of non-viral hepatitis in children. In response, Defendants assured FDA that they would complete a thorough recall of all Re^{2}al Water.

53. Despite such assurances, FDA's subsequent recall audit revealed that several distributors and retail establishments appeared to be unaware of the recall.

54. During the inspections, FDA investigators received conflicting information from Defendant Blain K. Jones about ingredients, manufacturing processes, and manufacturing and

processing dates for Re^{2}al Water and E^2 Concentrate. For example, Blain K. Jones initially stated that the 5-gallon containers of Re^{2}al Water were manufactured only in the Mesa Facility in November 2020, but FDA investigators later determined that the Henderson Facility was Defendants' only facility capable of bottling 5-gallon containers of Re^{2}al Water. Additionally, Blain K. Jones stated that Defendants' E^2 Concentrate had only been manufactured before August 2020, at a prior Las Vegas location. FDA investigators later determined that Defendants manufactured E^2 Concentrate at the Henderson Facility at least three times since September 2020. Blain K. Jones also denied any change in the formulation of Defendants' Re^{2}al Water, but FDA investigators later determined that Defendants had changed the formulation in November 2020 because of customer complaints regarding taste and possible illness.

55. Based on the foregoing, Plaintiff believes that, unless restrained by this Court, Defendants will continue to violate the Federal Food, Drug, and Cosmetic Act in the manner set forth above.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

I. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, cease manufacturing, processing, preparing, bottling, packing, labeling, holding, or distributing articles of food, unless and until Defendants' facilities, methods, processes, and controls used to manufacture, process, prepare, bottle, pack, labeling, hold, and distribute articles of food are established, operated, and administered in conformity with the Federal Food, Drug, and Cosmetic Act and applicable regulations, in a manner acceptable to FDA; and

II. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, be restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

a. Violating 21 U.S.C. § 331(uu), by operating a facility that manufactures, processes, packs, or holds food for sale in the United States, and not doing so in compliance with the hazard analysis and risk-based preventive controls requirements in 21 U.S.C. § 350g; and

b. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4) and/or misbranded within the meaning of 21 U.S.C. § 343; and

c. Violating 21 U.S.C. § 331(k), by causing articles of food that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) and/or misbranded within the meaning of 21 U.S.C. § 343; and

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' place(s) of business and all records relating to the manufacture, processing, preparing, bottling, packing, labeling, holding, and distribution of Defendants' products to ensure continuing compliance with the terms of the injunction, and that the Defendants bear the costs of such inspections at the rates prevailing at the time of the inspection(s) are accomplished; and

IV. Award Plaintiff costs incurred in pursuing this action, including the costs of investigation to date; and

V. Order such other and further equitable relief as this Court deems just and proper.

Dated this 19th day of May, 2021.

Respectfully submitted,

CHRISTOPHER CHIOU
Acting United States Attorney
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By: /s/ Troy Flake

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